"Cystic Fibrosis Foundation

November 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration

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5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 97N-0023

Dear Sir or Madam:

We are writing to share our comments on the proposed rule regarding "Use of Ozone-Depleting Substances; Essential Use Determinations," Docket No. 97N-0023. We are pleased that the agency has taken into consideration many of our concerns about the phasing out of products using chlorofluorocarbons (CFC's), or ozone-depleting substances (ODS), that are essential for health purposes.

As we stated in our comments on April 7, 1997 in response to the Advanced Notice of Proposed Rulemaking (ANPR), we are concerned about the impact of the FDA's efforts to minimize the use of CFC's in medical products and strive to make sure that people with cystic fibrosis (CF) are not adversely impacted by these changes. With over 21,000 people with CF in the U.S., these patients use metered dose inhalers and nasal steroids on a daily basis to help control the progression of their lung disease. The CF Foundation supports the efforts of the U.S. government to provide a safe environment for the public, and applauds efforts to remove CFC's from the atmosphere. However, we strongly urge that this transition not create new health risks for people with CF.

We are pleased with the proposed rule and believe that the agency has addressed many of our concerns to the ANPR. We support the agency's decision to no longer use a therapeutic class approach, but rather a moiety-by-moiety approach, to determine whether the use of an ozone-depleting substance (ODS) in a medical product remains essential. We also agree with the agency's decision to require more than one acceptable non-ODS alternative per active moiety to be marketed before considering removal of an essential use designation for the same active moiety if that active moiety is represented by multiple products or multiple strengths.

We have evaluated the impact on the CF population of the removal of all CFC-containing nasal steroids in current Sec. 2.125(e). We agree that there are adequate alternative products on the market for people with CF, which do not contain ODS. However, there is only one nasal steroid product that is approved for use in pediatric patients as young as four years of age. Therefore, we urge the FDA to consider the impact on pediatric patients of the withdrawal of all CFC-containing nasal steroid products at this time to ensure that sufficient alternatives exist for all ages. This is in keeping with the criteria FDA must consider before removing an essential-use designation to make sure the alternatives are appropriate for the same indication, which should include concerns regarding pediatric labeling.

97N-0023

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With regard to the criteria used to define a subpopulation, we recommend that the agency maintain sufficient flexibility regarding the minimum number of people who constitute a subpopulation. Rather than focusing on the precise number of people who constitute a subpopulation, we urge the FDA to consider the severity of the impact on any patients who could be harmed by lack of a medication due to compliance with the rules to eliminate the use of ODS.

For example, the Cystic Fibrosis Foundation is concerned about the impact of an agricultural pesticide using the bacterium, *Burkholderia cepacia*, on people with CF. While this naturally-occurring microorganism does not impact the majority of healthy people, for people with CF, it is very dangerous. And, for the few thousand people with CF who have acquired the bacterium, it is lethal. While the number of patients affected by this bacterium is relatively small, its impact on these patients is life-threatening and must be avoided. We do not believe that any patient should be harmed by environmental use of this pesticide. Likewise, with regard to the phase-out of ODS-containing medical products, we believe the FDA should address the impact of the lack of CFC-free medical alternatives on any patient group, regardless of the size of the patient population involved, particularly if the disease is life-threatening to begin with and a change in therapy puts them at greater risk of illness.

While we support the agency's decision to require compelling evidence of need before a new product containing CFC's can be approved for essential use, we believe the FDA should remain open to the potential benefits of such new products. While the approval of such products seems contrary to efforts to ban the use of all CFC's under the Montreal Protocol, we believe the FDA should openly consider the use of new technology which may require CFC's or other ODS if they bring about compelling therapeutic benefits to a significant, albeit small, subpopulation of patients.

We appreciate the FDA's leadership role in facilitating the efforts of government, health care providers and patients to ensure a healthy transition to CFC-free products. While we recognize that this is not the government's primary role, we urge the FDA to outline clear deadlines and strategies for complete transition from CFC products to new products to facilitate necessary education for health professionals and patients.

We appreciate the opportunity to comment on the proposed rule and would be pleased to answer any questions.

Sincerely,

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